IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	)	
Plaintiff,	)	
v.	)	C. A. No. 09- 608-JJF
GLENMARK GENERICS INC., USA,	)	
Defendant.	)	

DEFENDANT GLENMARK GENERICS INC., USA'S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant, Glenmark Generics Inc., USA ("Glenmark") by and through their undersigned counsel, hereby files its Answer, Affirmative Defenses, and Counterclaims to the Complaint of Plaintiff, Smithkline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), as follows:

THE PARTIES

1. Glenmark is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1 of the Complaint, and therefore denies said allegations.

2. Paragraph 2 is admitted in part and denied in part. Glenmark admits that Glenmark Generics Inc., USA is a Delaware corporation having a place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. The remaining allegations of paragraph 2 are denied.

NATURE OF THE ACTION

3. Paragraph 3 contains conclusions of law to which no response is required. To the extent a response is necessary, said allegations are denied.

JURISDICTION AND VENUE

4. Paragraph 4 contains conclusions of law to which no response is required. To the extent a response is necessary, said allegations are denied.

5. Paragraph 5 is admitted in part and denied in part. Glenmark admits that the Court has personal jurisdiction for purposes of this lawsuit only. The remaining allegations of paragraph 5 are denied.

6. Admitted for purposes of this lawsuit only.

THE PATENTS

7. Paragraph 7 is admitted in part and denied in part. On information and belief, Glenmark admits that U.S. Patent No. 6,166,046 ("the '046 Patent") is entitled "Combination of Atovaquone with Proguanil for the Treatment of Protozoal Infections," that it issued on December 26, 2000, and that a copy of the '046 Patent is attached to the Complaint as Exhibit A. Glenmark further admits that an assignment on file with the U.S. Patent and Trademark Office ("USPTO") lists GSK as the assignee of the '046 Patent as of March 31, 2001. The remaining allegations of paragraph 7 are denied.

8. Paragraph 8 is admitted in part and denied in part. On information and belief, Glenmark admits that U.S. Patent No. 6,291,488 ("the '488 Patent") is entitled "Preventing Protozoal Infections," that it issued on September 18, 2001, and that a copy of the '488 Patent is attached to the Complaint as Exhibit B. Glenmark further admits that an assignment on file with the USPTO lists GSK as the assignee of the '488 Patent as of March 31, 2001. The remaining allegations of paragraph 8 are denied.

9. Paragraph 9 is admitted in part and denied in part. On information and belief, Glenmark admits that U.S. Patent No. 5,998,449 ("the '449 Patent") is entitled "Combination of Atovaquone with Proguanil for the Treatment of Protozoal Infections," that it issued on December 7, 1999, and that a copy of the '449 Patent is attached to the Complaint as Exhibit C. Glenmark further admits that an assignment on file with the USPTO lists GSK as the assignee of the '449 Patent as of March 31, 2001. The remaining allegations of paragraph 9 are denied.

COUNT I – INFRINGEMENT OF THE '046 PATENT

10. Paragraph 10 is admitted in part and denied in part. Glenmark admits that it submitted ANDA 91-211 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act seeking approval to engage in the commercial manufacture, use, offer for sale and sale of tablets containing 250 milligrams of atovaquone / 100 milligrams of proguanil hydrochloride per tablet ("the Accused Product"). Glenmark further admits that ANDA 91-211 seeks FDA approval to market the Accused Product as an AB-rated generic drug based on Malarone® tablets containing 250 milligrams of atovaquone / 100 milligrams of proguanil hydrochloride per tablet ("Malarone") prior to the expiration of the '046 Patent.

11. Paragraph 11 is admitted in part and denied in part. Glenmark admits that ANDA 91-211 contains a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that, to the best of Glenmark Generic Ltd.'s knowledge, the '046 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale within the United States, or importation into the United States of the Accused Product. Glenmark is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 11, and therefore denies said allegations.

12. Denied.

13. Paragraph 13 is admitted in part and denied in part. Glenmark admits that it was aware of the '046 Patent as of the date it filed ANDA 91-211. The remaining allegations of paragraph 13 are denied.

14. Denied.

COUNT II – INFRINGEMENT OF THE '488 PATENT

15. Paragraph 15 is admitted in part and denied in part. Glenmark admits that it submitted ANDA 91-211 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act seeking approval to engage in the commercial manufacture, use, offer for sale and sale of the Accused Product. Glenmark further admits that ANDA 91-211 seeks FDA approval to market the Accused Product as an AB-rated generic drug based on Malarone prior to the expiration of the '488 Patent.

16. Paragraph 16 is admitted in part and denied in part. Glenmark admits that ANDA 91-211 contains a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that, to the best of Glenmark Generic Ltd.'s knowledge, the '488 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale within the United States, or importation into the United States of the Accused Product. Glenmark is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 16, and therefore denies said allegations.

17. Denied.

18. Paragraph 18 is admitted in part and denied in part. Glenmark admits that it was aware of the '488 Patent as of the date it filed ANDA 91-211. The remaining allegations of paragraph 18 are denied.

19. Denied.

COUNT III – INFRINGEMENT OF THE '449 PATENT

20. Paragraph 20 is admitted in part and denied in part. Glenmark admits that it submitted ANDA 91-211 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act seeking approval to engage in the commercial manufacture, use, offer for sale and sale of the Accused Product. Glenmark further admits that ANDA 91-211 seeks FDA approval to market the Accused Product as an AB-rated generic drug based on Malarone prior to the expiration of the '449 Patent.

21. Paragraph 21 is admitted in part and denied in part. Glenmark admits that ANDA 91-211 contains a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that, to the best of Glenmark Generic Ltd.'s knowledge, the '449 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale within the United States, or importation into the United States of the Accused Product. Glenmark is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 21, and therefore denies said allegations.

22. Denied.

23. Paragraph 23 is admitted in part and denied in part. Glenmark admits that it was aware of the '449 Patent as of the date Glenmark filed its § 505(j)(2)(A)(vii)(IV) certification with respect to the '449 Patent. The remaining allegations of paragraph 23 are denied.

24. Denied.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '449 PATENT

25. Glenmark repeats and realleges its responses to paragraphs 1-24 of the Complaint.

26. Paragraph 26 is admitted in part and denied in part. Glenmark admits that it submitted ANDA 91-211 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act

seeking approval to engage in the commercial manufacture, use, offer for sale and sale of the Accused Product. Glenmark further admits that ANDA 91-211 seeks FDA approval to market the Accused Product as an AB-rated generic drug based on Malarone prior to the expiration of the ’046 Patent, the ’488 Patent, and the ’449 Patent.

27. Denied.

28. Denied.

29. Paragraph 29 is admitted in part and denied in part. Glenmark admits that an actual and justiciable controversy exists between Glenmark and GSK. The remaining allegations of paragraph 29 are denied.

30. Paragraph 30 is admitted in part and denied in part. Glenmark admits that it was aware of the ‘449 Patent as of the date Glenmark filed its § 505(j)(2)(A)(vii)(IV) certification with respect to the ’449 Patent. The remaining allegations of paragraph 30 are denied.

31. Denied

PRAYER FOR RELIEF

Glenmark denies that GSK is entitled to any relief requested in the Complaint.

AFFIRMATIVE DEFENSES

First Affirmative Defense - Non-Infringement

32. Glenmark has not infringed, either directly, contributorily, or by inducement, the claims of the ’046 Patent, either literally or under the doctrine of equivalents.

33. Glenmark has not infringed any claim of the ’046 Patent.

34. Glenmark has not infringed, either directly, contributorily, or by inducement, the claims of the ’488 Patent, either literally or under the doctrine of equivalents.

35. Glenmark has not infringed any claim of the ’488 Patent.

36. Glenmark has not infringed, either directly, contributorily, or by inducement, the claims of the ’449 Patent, either literally or under the doctrine of equivalents.

37. Glenmark has not infringed any claim of the ’449 Patent.

Second Affirmative Defense - Invalidity

38. Each claim of the ’046 Patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112 and/or 119.

39. Each claim of the ’488 Patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112 and/or 119.

40. Each claim of the ’449 Patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112 and/or 119.

Third Affirmative Defense – No Relief Available

41. GSK is barred from obtaining the requested relief pursuant to one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112 and/or 119.

42. GSK has not suffered any damages.

43. GSK is not suffering any irreparable injury.

44. Glenmark reserves the right to assert such other defenses that may appear as discovery proceeds in this case.

Fourth Affirmative Defense – Additional, Unasserted Defenses

45. Defendant presently lacks sufficient knowledge or information on which to form a belief as to whether he may have additional, unasserted defenses. Accordingly, Defendant

reserves the right to assert additional defenses in the event discovery indicates that doing so would be appropriate.

GLENMARK'S COUNTERCLAIMS

For its counterclaims against Smithkline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), Glenmark Generics Inc., USA ("Glenmark") alleges as follows:

The Parties

46. Glenmark Generics Inc., USA is a Delaware corporation with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

47. On information and belief, Smithkline Beecham Corporation d/b/a GlaxoSmithKline is a Pennsylvania corporation with its principal place of business located at One Franklin Plaza, Philadelphia, Pennsylvania 19102.

Jurisdiction and Venue

48. Jurisdiction of this Court is based upon 28 U.S.C. §§ 1331, 1338(a), and 1367(a); the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*; and 35 U.S.C. § 271(e)(2).

49. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and/or 1400(b).

50. This is an action based on an actual and justiciable controversy between Glenmark and GSK concerning the invalidity and/or infringement of U.S. Patent No. 6,166,046 ("the '046 Patent"), U.S. Patent No. 6,291,488 ("the '488 Patent"), and U.S. Patent No. 5,998,449 ("the '449 Patent") (collectively, "the asserted patents").

Background

51. On information and belief, the '046 Patent, entitled "Combination of Atovaquone with Proguanil for the Treatment of Protozoal Infections," issued on December 26, 2000.

52. On information and belief, the ’488 Patent, entitled “Preventing Protozoal Infections,” issued on September 18, 2001.

53. On information and belief, the ’449 Patent, entitled “Combination of Atovaquone with Proguanil for the Treatment of Protozoal Infections,” issued on December 7, 1999.

54. On information and belief, GSK is the current owner by assignment of the asserted patents.

55. Glenmark denies that it infringes any valid and enforceable claim of the asserted patents.

56. Based on GSK’s filing of the Complaint, and Glenmark’s denial thereof, an actual controversy has arisen and now exists between the parties as to whether Glenmark has infringed any valid and enforceable claims of the asserted patents.

57. Unless GSK is enjoined, Glenmark believes GSK will continue to assert that Glenmark is infringing claims of the asserted patents and will continue to interfere with Glenmark’s business with respect to the manufacture, use, offer for sale, and sale of tablets containing 250 milligrams of atovaquone / 100 milligrams of proguanil hydrochloride per tablet (“the Accused Product”).

58. Glenmark will be irreparably harmed if GSK is not enjoined from asserting the ’046 Patent, the ’488 Patent, and the ’449 Patent and from interfering with Glenmark’s business.

FIRST COUNTERCLAIM

Declaratory Judgment of Non-Infringement

59. Glenmark incorporates paragraphs 47-57 of the Counterclaims as if fully set forth herein.

60. Glenmark has not infringed, and is not infringing, and has not induced or contributed to, and is not inducing or contributing to the infringement of any claim of the accused patents, either literally or under the doctrine of equivalents.

61. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Glenmark requests a declaration from the Court that Glenmark does not infringe the claims of the asserted patents.

SECOND COUNTERCLAIM

Declaratory Judgment of Invalidity

62. Glenmark incorporates paragraphs 47-60 of the Counterclaims as if fully set forth herein.

63. The claims of the asserted patents are invalid for failure to satisfy one or more of the conditions for patentability specified under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112 and/or 119.

64. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Glenmark requests a declaration from the Court that the claims of the asserted patents are invalid.

PRAYER FOR RELIEF

WHEREFORE, Glenmark respectfully prays that this Court enter judgment in its favor and grant the following relief:

A. Dismissing GSK's Complaint with prejudice and denying each and every prayer for relief contained therein;

B. Declaring that Glenmark has not infringed any claim of the '046 Patent, the '488 Patent, and the '449 Patent, and that Glenmark has a lawful right to manufacture,

market, and sell tablets containing 250 milligrams of atovaquone / 100 milligrams of proguanil hydrochloride per tablet;

C. Declaring that the claims of the ’046 Patent, the ’488 Patent, and the ’449 Patent are invalid;

D. Declaring that the claims of the ’046 Patent, the ’488 Patent, and the ’449 Patent are void and unenforceable;

D. Enjoining GSK, its officers, employees, agents, representatives, attorneys and others acting on its behalf, from threatening or initiating infringement litigation against Glenmark or its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Glenmark, or charging them either orally or in writing with infringement of any patent asserted against Glenmark;

I. Awarding to Glenmark such further relief as this Court may deem necessary, just, and proper.

Dated: October 8, 2009

BLANK ROME LLP

/s/ Steven L. Caponi

By: _____

Steven L. Caponi, I.D. No. 3484
1201 North Market Street
Suite 800
Wilmington, DE 19801
(302) 425-6400
Caponi@BlankRome.com

and

H. Keeto Sabharwal
Daniel E. Yonan
BLANK ROME LLP
600 New Hampshire Ave., NW
Washington, DC 20037
(202) 772-5800
Sabharwal@BlankRome.com
Yonan@BlankRome.com

Attorneys for Defendant, Glenmark Generics Inc., USA